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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,239	08/27/2003	Steve Haycs	3413.001	6020

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EXAMINER

CARRILLO, BIBI SHARIDAN

ART UNIT PAPER NUMBER

1746

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/649,239

Applicant(s)

HAYES ET AL.

Examiner

Sharidan Carrillo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/27/2005</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 8-15 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an aqueous cleaning solution, does not reasonably provide enablement for any type of cleaning solution. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims embrace an invention which contains any known cleaning solution, which could/can be selected from literally thousands. It does not appear to be feasible that any cleaning solution would function in the present invention. Further, for one skilled in the art to reproduce the present invention (which must be possible, if the specification is adequate), there would clearly be undue experimentation to do so in an attempt to figure out which cleaning solutions work and which ones do not.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1 and 8 are indefinite because of steps e and d respectively. Specifically, it is unclear where the paraffin containing aqueous cleaning solution is passed to after leaving the mold receiving chamber. Claim 1, steps b and d are indefinite because "the tissue processing mold" lacks positive antecedent basis. Claim 1 is indefinite because it is unclear what one would consider as a "sufficient amount". Claims 1 and 8 are indefinite because it is unclear what is meant by "substantially free".

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-4 and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinhardt et al. (US2004/0002163).

Reinhardt teaches a de-paraffinizing station 140. Reinhardt teaches removing paraffin from the tissue embedded mold by treating with a plurality of wash dispensing nozzles 142 directed downward at an angle to a specific slide (paragraph 34). In paragraph 35, Reinhardt teaches that the deparaffinizing fluid is an aqueous based heated fluid which contains one or more non-ionic surfactants. Figs. 3 and 3A teaches a deparaffinizing station comprising a modular compartment. Reinhardt teaches placing the tissue samples in the modular compartment and treating with the heated aqueous solution to remove the paraffin. Reinhardt fails to teach repeating the steps, as recited in claims 1-2, 8 and 10 or agitating the solution, as recited in claims 1-2, 8 and 10. However, it would have been well within the level of the skilled artisan to have modified the method of Reinhardt to include repeating the steps and agitation for purposes of effectively removing the paraffin from the tissue mold. Additionally, the step of agitation for purposes of enhancing contaminant removal in a cleaning process is notoriously well known and convention in the art (6432215). In reference to claims 3-4, 9, and 11-12, refer to paragraph 35. Reinhardt fails to teach heating the fluid to the boiling point. However, since Reinhardt teaches heating the fluid to a temperature greater than the

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melting point of the paraffin, it would have been within the level of the skilled artisan to heat the fluid to higher temperatures in order to melt the paraffin.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kerrod teaches a tissue processing apparatus and method. Gamache et al. teach a wax device and method. Sample et al. teach a paraffin removal process. Ferrari teach treating histological tissue. Wang et al. teaches treatment of paraffin embedded tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharidan Carrillo whose telephone number is 571-272-1297. The examiner can normally be reached on M-W 6:30-4:00pm, alternating Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Barr can be reached on 571-272-1414. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharidan Carrillo

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Primary Examiner  
Art Unit 1746

bsc



SHARIDAN CARRILLO  
PRIMARY EXAMINER